

02N-0278_emc-000190.txt

From: Andrew Wilson [awilson@hortcouncil.ca]
Sent: Friday, May 14, 2004 1:05 PM
To: fdadockets@oc.fda.gov
Cc: Anne Fowlie; Heather Gale; ddempster@cpma.ca; jeffbro@mts.net
Subject: Dockets No. 2002N-0276 and 2002N-0278

To whom it may concern.

Attached to this message is a Microsoft Word document containing the Canadian Horticultural Council's comments on the FDA's Interim Final Rule Concerning Registration of Food Facilities (Docket 2002N-0276) and the Joint Food and Drug Administration - Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes (Docket 2002N-0278).

While every effort has been made to ensure that this document gets through, please contact Andrew Wilson at awilson@hortcouncil.ca should there be any problems with this electronic submission.

Thank-you,

Andrew Wilson
Canadian Horticultural Council

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www.fda.gov/oc/bioterrorism/titleIII.html#registration
www.fda.gov.dockets/ecomments

May 14, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0276
ATTN: Docket No. 02N-0278

Subject:

Rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the [US] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Bioterrorism Act)

Docket No. 02N-0276, Section 305 (Registration)
Docket No. 02N-0278, Section 307 (Prior Notice)

To Whom It May Concern:

We appreciate the opportunity to submit comments to the above referenced items on behalf of the Canadian Horticultural Council.

Sincerely,

Anne Fowlie
Executive Vice President
Canadian Horticultural Council

attachment

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ATTN: Docket No. 02N-0276
ATTN: Docket No. 02N-0278

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May 14, 2004

Comments of The Canadian Horticultural Council on The Interim Final Rule concerning Registration of Food Facilities and the Joint Food and Drug Administration – Customs and Boarder Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes under the [U.S.] Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)

The Canadian Horticultural Council appreciates the opportunity to provide additional comments on the above-mentioned rules during the reopening of the comment period, as published by the Food and Drug Administration, Department of Health and Human Services, in the *Federal Register of April 14, 2004* (Volume 69, Number 62). We respectfully request that this single submission be considered for both dockets.

While we support the objectives of the [U.S.] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)* and share concerns relative to perimeter and border security as well as food safety we take issue with certain aspects of the proposed rules. CHC expressed these concerns in a submission dated "April 3, 2003", and we trust that the FDA will address the issues identified at that time. The following comments will focus primarily on the issues identified for comment by the FDA.

About The Canadian Horticultural Council

The Canadian Horticultural Council (CHC) is a voluntary, not-for-profit, national association representing the diverse sector of Canadian agriculture known as horticulture. The CHC has been committed to promoting the interests of its members since 1922.

The CHC's members are primarily involved in the production and packing of over 120 horticulture crops comprised of fruit, vegetables, flowers and ornamental plants. We have 105 members from across Canada as well as three associate members from the United States.

The CHC's mission is a commitment to advance the growth and economic viability of horticulture by encouraging cooperation and understanding to build national consensus on key issues so as to deliver unified and clear representation to governments and other national and international parties.

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**Docket No. 02N-0276
Registration of Food Facilities**

COSTS RELATED TO HIRING A US AGENT

The cost to CHC members for hiring a U.S. agent ranged from \$100.00 to \$935.00, with most responses being in the \$700.00 to \$900.00 range (all figures are given in U.S. dollars.) This cost places a disproportionate burden on smaller companies and for companies that ship fresh produce for a limited time during the year.

NUMBER OF FACILITIES THAT HAVE HIRED A U.S. AGENT

It appears that almost all of the Canadian shippers who do business in the US have hired a U.S. agent. A number of farms that grow and pack their own produce have also hired a U.S. agent based on advice from border brokers who have informed farmers that this was necessary. Some growers have incurred costs of more than \$500 U.S. for a "farm registration". CHC is not currently aware of any facility that has decided to halt shipments to the United States because of the requirement to hire a U.S. agent.

CHC members have also identified other issues related to the Interim Final Registration Rule. These issues include:

- CHC members request changes to the requirement for a US agent, and suggests that a suitable alternative would be for facilities to offer a telephone contact number that can be reached on a 24-hour basis.
- There has been a great deal of confusion related to the requirements for farms that grow and pack their own produce. Canadian government officials have indicated that these farms are exempt from this requirement and the costs associated with it, but border brokers have been providing advice to the contrary. The CHC requests that clarification be provided on this issue at the earliest possible date.

**Docket No. 02N-0278
Prior Notice of Imported Food Shipments**

COST OF COMPLYING WITH PRIOR NOTICE REQUIREMENTS

Despite the fact that most exporters are filing notices by themselves electronically, they are also incurring additional charges related to prior notice requirements from their border brokers. These costs are separate from the costs of hiring a U.S. agent. Total payments to U.S. companies for prior notice services are a substantial expense for the companies involved.

In addition to the direct costs per load charges, shippers face a number of additional costs to comply with the prior notice requirements. These costs

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include the time required for dealers and staff to file prior notices, and costs for upgrading EDI systems.

CHC members have also identified a number of other issues related to the Prior Notice requirements. These include:

- CHC members and their customers in the United States would be better served if the prior notice period was further reduced to one hour from four hours. This reduction would facilitate the movement of highly perishable goods, and would be better suited to the Just In Time delivery systems used in the produce industry.
- Members would also appreciate any changes that would help reduce the charges being incurred due to prior notice requirements.
- CHC members have identified a need for additional information about current levels of non-compliance with the Prior Notice rules so that issues can be better addressed.

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